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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,093	11/16/2000	Frank Butaric	CRD-834	5116

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EXAMINER

MILLER, CHERYL L

ART UNIT PAPER NUMBER

3738

DATE MAILED: 05/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/714,093

Applicant(s)

BUTARIC ET AL. *BT*

Examiner

Cheryl L. Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other:

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Line 1 of the abstract recites the phrase "In accordance with the present invention". This language is improper and should be deleted.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "41" has been used to designate both flanges (pg.16, line 23) and interior surface (pg.12, line 17). Other similar errors occur throughout the specification. Reference characters "1 and 2" have been used to designate both iliac arteries (pg.17, lines 29, 32) and femoral arteries (pg.18, line 1). It is suggested to change "femoral arteries" to --iliac arteries-- on page 18, line 1. Reference character "300" has been used to designate both infrarenal neck (fig.19, 20; pg.18, line 11) and delivery apparatus (fig.23, 25; pg.16, line 32; pg.17, lines 2, 6). Reference characters "300" (figs.19, 20; pg.18, line 11) and "3" (figs.16-18; pg.17, line 29) have both been used to designate infrarenal neck. Reference characters "130" (fig.15; pg.16, lines 6, 8, 13) and "300" (figs.23, 25; pg.16, line 32; pg.17, lines 2, 6) have both been used to designate delivery apparatus. Reference character "132" has been used to designate both delivery apparatus (figs.17, 18; pg.18, line 1) and outer sheath (fig.15; pg.16, lines 8, 12, 14). Reference characters "132" (pg.16, line 8, 12, 14) and "332" (pg.17, lines 2, 7) have both been used to designate outer sheath. Reference characters "82 and 84" has been used to designate different parts in figure 8, than in figure 9.

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It is suggested to delete 82 and 84 from figure 8. Reference characters "10" and "12" and "40" and "80" have all been used to designate stent. It is confusing to the examiner, which stent applicant is referring to throughout the specification. Phrase "precursor stent" should be used each time (10) is mentioned throughout the specification. Phrase "member" should be used each time (12) is mentioned throughout the specification. Phrase "stent" should be used each time (40) is mentioned throughout the specification. Phrase "stent-graft" should be used each time (80) is mentioned throughout the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 43A, 43B (figs. 4, 15) and 72 (fig. 6). A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. It is suggested to assign reference numeral 43A to interior surface and reference numeral 43B to exterior surface on page 12, line 17.

Claim Objections

2. Claim 1 is objected to because of the following informalities: Line 1 recites "An hollow substantially cylindrical radially expandable stent", which contains improper grammar and should be changed to --A hollow substantially cylindrical radially expandable stent--. Appropriate correction is required.

3. Claims 13, 14, and 21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 13 is identical to claim 9 and does not further limit. Claim 14 is identical to

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limitation in parent claim 6, and does not further limit. Claim 21 is identical to parent claim 14 and does not further limit.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 5 and 10 recite the limitation "said distal and proximal hoops" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "said distal and proximal hoops" to recite --said distal and proximal end hoops--, in order to be consistent with terminology of parent claims 1 and 6 respectively.

7. Claim 6 recites the limitation "said stent" in line 1. Claim 6 recites the limitation "said graft member" in line 3. Claim 6 recites the limitation "said body" in line 13. There is insufficient antecedent basis for these limitations in the claim. It is suggested to change "said stent" to recite --said stent graft--. It is also suggested to rearrange limitations so that limitation b becomes limitation a, limitation c becomes limitation b, and limitation a becomes limitation c.

Claims 7-15 and 18-22 depend upon claim 6, and inherit all problems associated with the parent claim.

Claims 6, 14, and 21 are Markush type claims, and should recite the language --consisting of--. It is suggested to change "selected from the group of materials comprising" to recite --selected from the group of materials consisting of--.

8. Claim 11 recites the limitation "said exterior surface" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change one of the following: "said exterior

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surface” to recite --said exterior--, or in parent claim 6, change “an interior and an exterior” to recite --an interior surface and an exterior surface--.

9. Claim 15 recites the limitation "said tab" and “said second leg” and “said staple” in lines 1, 2, and 2 respectively. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 16 recites the limitation "said staple" in line 1. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 17 recites the limitation "said exterior surface" in line 9. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change one of the following: “said exterior surface” to recite --said exterior--, or change in line 5, “an exterior” to recite --an exterior surface--.

12. Claim 20 recites the limitation "The stent graft" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change “The stent graft” to recite --the stent--.

13. Claim 22 recites the limitation "said staple" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

14. Claim 17 of this application conflict with claim 14 of Application No. 09/714,080. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Berry et al. (USPN 6,231,598 B1). Berry discloses a stent, which includes all limitations recited in the claims. Berry discloses a stent (col.8, lines 36-39) having a plurality of hoops (13), comprising a plurality of interconnected struts (14), the stent having a proximal (63) and a distal end hoop (63'), the end hoops having greater radial and longitudinal strength (col.11, lines 50-55; col.12, lines 4-30, 45-52; col.13, lines 49-52; col.21, lines 40-45; col.22, lines 15-25, 57). Berry discloses a plurality of sinusoidal (75), (108), rings (21) connecting adjacent hoops to one another (col.9, lines 1-3; col.10, lines 26-32).

Referring to claim 2, Berry discloses a diamond pattern on hoops (figs.15, 16, 17, 18, 20).

Referring to claims 3-4, Berry discloses a self-expanding stent, made of superelastic nickel titanium (col.8, lines 60-63; col.18, lines 45-66).

Referring to claim 5, Berry discloses an end hoop having a larger diameter than an adjacent hoop (col.22, lines 1-7).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berry et al. in view of Gittings et al. (USPN 6,361,557 B1). Berry discloses the stent substantially as claimed. Berry discloses radiopaque markers (col.19, lines 37-50; col.20, lines 2-6) positioned on the stent, however does not disclose the markers as being staples. Gittings teaches a stent having radiopaque staples in order to attach a stent to a graft (col.3, lines 32-49, 61-62; col.4, lines 40-42; col.5, lines 3-8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Gittings' teaching of a radiopaque staple, with Berry's radiopaque markers on a stent, in order to provide radiopacity and attachment means to a graft at the same time.

19. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty et al. (USPN 6,193,745 B1) in view of Bedi et al. (USPN 4,627,437). Fogarty discloses a stent graft substantially as claimed. Fogarty discloses a stent graft for insertion into body lumens (col.1, lines 10-16; col.3, lines 10-12; col.8, lines 55-60) comprising a cylindrical stent having interconnected struts (12), (112), a strut having adjacent first, and second apertures for attachment (214), (228), (col.6, lines 16-17, 29-30; fig.13A, 14), and a graft member (18), (172), covering a surface of the stent (col.4, lines 46-49; fig.1). Fogarty discloses a staple for attaching the stent to the graft (col.11, lines 55-60; col.17, lines 38-42). Fogarty does not however, disclose an orientation for the staple, nor does Fogarty disclose a third middle aperture. Bedi teaches staple orientation wherein the staple has a crown (68) and two legs (66) and is used to fasten together two materials (col.4, lines 15-17). Bedi teaches an attachment strut (62) having a first, second, and middle aperture (77), (fig.12). Bedi teaches a staple orientation wherein a leg (66) extends through a material and through first aperture (76), another leg (66) extends through a material and through second aperture (76), both legs then bent towards the crown (68), and extending through a middle aperture (fig.12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Bedi's teaching of staple orientation and a middle aperture for the

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purpose of fastening two materials together, with Fogarty's stent graft, in order to securely fasten the stent to the graft.

20. Claims 6-14 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berry et al. in view of Fogarty et al. (USPN 6,193,745 B1). Berry discloses the invention substantially as claimed. Referring to claims 6, 11, 14, 18, and 21, Berry discloses a stent (col.8, lines 36-39) having a plurality of hoops (13), comprising a plurality of interconnected struts (14), the stent having a proximal (63) and a distal end hoop (63'), the end hoops having greater radial and longitudinal strength (col.11, lines 50-55; col.12, lines 4-30, 45-52; col.13, lines 49-52; col.21, lines 40-45; col.22, lines 15-25, 57). Berry discloses a plurality of sinusoidal (75), (108), rings (21) connecting adjacent hoops to one another (col.9, lines 1-3; col.10, lines 26-32). Berry does not however, disclose an attached graft member, or a preferred graft member material. Fogarty teaches in the same field of endeavor, a stent graft, having a graft member (18), (172), attached to a stent (fig.1; col.4, lines 46-49), covering substantially all of an exterior surface of a stent (fig.1, col.4, lines 45-50; col.9, lines 3-5), wherein the graft is made of a material selected from the group of materials consisting of Dacron, Teflon, woven polyester, and polyurethane (col.12, lines 53-54, 58-59; col.14, lines 25-27, 36-37, 62-63) for the purpose of providing protection and biocompatibility. It would have been obvious to one having ordinary skill in the art at the time of the invention to combine Fogarty's teaching of attaching a graft to a stent and selection of graft material, with Berry's stent configuration, in order to provide increased protection and biocompatibility.

Referring to claim 7, Berry discloses a diamond pattern on hoops (figs.15, 16, 17, 18, 20).

Referring to claims 8-9, 12-13, and 19-20, Berry discloses a self-expanding stent, made of superelastic nickel titanium (col.8, lines 60-63; col.18, lines 45-66).

Referring to claim 10, Berry discloses an end hoop having a larger diameter than an adjacent hoop (col.22, lines 1-7).

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21. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berry et al. in view of Fogarty et al. as applied to claim 6 above, and further in view of Seedhom et al. (USPN 5,209,756). Berry in view of Fogarty discloses a stent graft substantially as claimed. Fogarty discloses a strut having a tab (col.18, lines 6-7, 15-17) for a staple (col.11, lines 55-60; col.17, lines 38-42). Fogarty does not however, disclose a tab having a notch. Seedhom teaches a staple (col.1, lines 20-22) and a tab (col.1, lines 24-32), wherein the tab has a notch (109), (fig.3, 10; col.3, lines 5-6). Seedhom teaches a second staple leg that abuts a notch (fig.1) for the purpose of providing a tight attachment and to guide the staple legs to the desired position (col.2, lines 56-61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Seedhom's teaching of a notched tab and staple orientation, with Berry in view of Fogarty's stent graft tabs and staple, in order to provide a tight attachment and guide for positioning staple.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

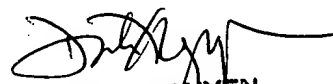
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl L. Miller

05/02/2002


DINH X. NGUYEN
PRIMARY EXAMINER